

JC09 Rec'd PCT/PTO 28 SEP 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International Application No. : PCT/US2004/009618
International Filing Date : 29 March 2004 (29.03.2004)
Earliest Priority Date : 28 March 2003 (28.03.2003)
Applicant(s) : C.R. BARD, INC. ET AL.
Title : METHOD AND APPARATUS FOR ADJUSTING
ELECTRODE DIMENSIONS

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Transmitted herewith for filing a Demand for International Preliminary Examination,
Amendments under Article 34 and Fee Calculation Sheet with Deposit Account
Authorization.

A check in the amount of \$923.00 is enclosed to cover the fee. If this is insufficient, please
charge any deficiency, or credit any overpayment in the total fees, to the account of Wolf,
Greenfield & Sacks, P.C., Deposit Account No. 23/2825.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application
Branch is respectfully requested to contact the undersigned collect at (617) 720-3500, Boston,
Massachusetts.

Respectfully submitted,



Eric L. Amundsen
Reg. No.: 46,518
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 720-3500
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DOCKET NO.: B1075.71014
DATE: 7 April 2005
Express Mail Label No.: EL960700821US

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of the Authority may be indicated by the applicant on the line below:

IPEA/US

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty

For International Preliminary Examining Authority use only

Identification of IPEA

Date of Receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION

Applicant's or agent's file reference
B1075.71014

International Application No.
PCT/US2004/009618

International Filing Date (day/month/year)
29 March 2004 (29.03.2004)

(Earliest) Priority date (day/month/year)
28 March 2003 (28.03.2003)

Title of Invention

METHOD AND APPARATUS FOR ADJUSTING ELECTRODE DIMENSIONS

Box No. II APPLICANT(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

C.R. BARD, INC.

730 Central Avenue

Murray Hill, New Jersey 07974

United States of America

Telephone No.:

Facsimile No.:

Teleprinter No.:

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

STEVENS-WRIGHT, Debbie

175 Candlestick Road

North Andover, Massachusetts 01845

United States of America

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

AMARA, Ryan

57 Beech Street

Tewksbury, Massachusetts 01876

United States of America

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

X Further applicants are indicated on a continuation sheet.

Form PCT/IPEA/401 (first sheet) ((January 2004)

Express Mail Label No. EL960700821US

See Notes to the demand form

| | | |
|--|--|--|
| Sheet No. 2 | | International application No. PCT/US2004/009618 |
| Continuation of Box No. II APPLICANT(S) | | |
| <i>If none of the following sub-boxes is used, this sheet is not to be included in the demand.</i> | | |
| Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.) BROWN, Erik 10928 SW Collina Avenue Portland, Oregon 97219 United States of America | | |
| State (i.e. country) of nationality: US | State (i.e. country) of residence: US | |
| Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.) MACADAM, David 5 Cyndy Lane Millbury, Massachusetts 01527 United States of America | | |
| State (i.e. country) of nationality: US | State (i.e. country) of residence: US | |
| Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.) | | |
| State (i.e. country) of nationality | State (i.e. country) of residence: | |
| Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.) | | |
| State (i.e. country) of nationality: | State (i.e. country) of residence: | |
| <input type="checkbox"/> Further applicants are indicated on another continuation sheet. | | |

Form PCT/IPEA/401 (continuation sheet) (January 1994; reprint January 1997) See Notes to the demand form

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCEThe following person is ☒ agent ☐ common representative

- And ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.
☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.
☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Attorney, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

MORRIS, James H.
 Wolf, Greenfield & Sacks, P.C.
 600 Atlantic Avenue
 Boston, Massachusetts 02210
 United States of America

Telephone No.:
(617) 720-3500Facsimile No.:
(617) 720-2441

Teleprinter No.:

☐ **Address for Correspondence:** Mark this check box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION**Statement concerning amendments:***

1. The applicant wishes the international preliminary examination to start on the basis of:

☐ the international application as originally filed

the description ☒ as originally filed to include the Rectification of Obvious Errors as filed on 01 July 2004
☐ as amended under Article 34

the claims ☐ as originally filed
☐ as amended under Article 19 (together with any accompanying statement)
☒ as amended under Article 34 to include the Rectification of Obvious Errors as filed on 01 July 2004

the drawings ☒ as originally filed to include the Rectification of Obvious Errors as filed on 01 July 2004
☐ as amended under Article 34

2. ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.3. ☐ The applicant wishes the start of the international preliminary examination to be postponed until the expiration of the applicable time limit under Rule 69.1(d).4. ☐ The applicant wishes the start of the international preliminary examination to start earlier than the expiration of the applicable time limit under Rule 69.1(d).

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: . . . English

- ☒ which is the language in which the international application was filed.
☐ which is the language of a translation furnished for the purposes of international search.
☐ which is the language of publication of the international application
☐ which is the language of the translation to be furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The filing of this demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the PCT.

Box No. VI CHECKLIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | | | |
|----|---|---|---|--------|
| 1. | translation of international application | : | | sheets |
| 2. | amendments under Article 34 | : | 6 | sheets |
| 3. | copy (or, where required, translation) of amendments under Article 19 | : | | sheets |
| 4. | copy (or, where required, translation) of statement under Article 19 | : | | sheets |
| 5. | letter | : | 4 | sheets |
| 6. | other (<i>specify</i>) | : | | sheets |

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Received not received

| | |
|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |

The demand is also accompanied by the item(s) marked below:

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> fee calculation sheet | 4. <input type="checkbox"/> statement explaining lack of signature |
| 2. <input type="checkbox"/> separate signed power of attorney | 5. <input type="checkbox"/> nucleotide and or amino acid sequence listing in computer readable form |
| 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: | 6. <input checked="" type="checkbox"/> other (<i>specify</i>): Transmittal letter Postcard Check |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).



AMUNDSEN, Eric L.
Agent for the Applicant

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND: _____

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b): _____

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. ☐ The applicant has been informed accordingly.

4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.

5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

6. ☐ The date of receipt of the demand is AFTER the expiration of the time limit under Rule 54bis.1(a) and item 7 or 8 below, does not apply.

7. ☐ The date of receipt of the demand is WITHIN the time limit under Rule 54bis.1(a) as extended by virtue of Rule 80.5.

8. ☐ Although the date of receipt of the demand is after the expiration of the time limit under Rule 54bis.1(a), the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau-use only

Demand received from IPEA on: _____

Form PCT/IPEA/401 (last sheet) (January 2004)

See Notes to the demand form

PCT

FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

For International Preliminary Examining Authority use only

International
Application No. PCT/US2004/009618Applicant's or agent's
File reference: B1075.71014

Date stamp of the IPEA

Applicant

C.R. BARD, INC. ET AL.

Calculation of prescribed fees

1. Preliminary examination fee

\$750.00
(USPTO
was not
ISA)

P

2. Handling fee

\$173.00

H

3. Total of prescribed fees

Add the amounts entered at P and H
and enter total in the TOTAL box

\$923.00

TOTAL

Mode of Payment

☐ authorization to charge deposit
account with the IPEA (see below)☐ cash☒ cheque☐ revenue stamps☐ postal money order☐ coupons☐ bank draft☐ other (specify):

Deposit Account Authorization (this mode of payment may not be available at all IPEAs)

The IPEA/US ☐ is hereby authorized to charge the total fees indicated above to my deposit account.☒ (this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit) is hereby
authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit
account.

23/2825

07 April 2005

Deposit Account Number

Date (day/month/year)

AMUNDSEN, Eric L.

Form PCT/IPEA/401 (Annex) (July 1998; reprint January 2000)

See notes to the fee calculation sheet

JC09 Rec'd PCT/PTO 28 SEP 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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International Application No. : PCT/US2004/009618
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Applicant(s) : C.R. BARD, INC. ET AL.
Title : METHOD AND APPARATUS FOR
ADJUSTING ELECTRODE DIMENSIONS

Authorized Officer : Astrid Lambertz

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Transmitted herewith for filing is a Response to Written Opinion with Amendments Under PCT Article 34(2)(b) with Substitute Sheet(s).

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned collect at (617) 646-8000, Boston, Massachusetts.

Respectfully submitted,



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600 Atlantic Avenue
Boston, Massachusetts 02210-2206
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DOCKET NO.: B1075.71014WO00

DATE: 7 April 2005

x04/07/05

Express Mail Label No.: EV 493480064 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International Application No.: PCT/US2004/009618
International Filing Date: 29 March 2004 (29.03.2004)
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ELECTRODE DIMENSIONS

Authorized Officer: Astrid Lambertz

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO WRITTEN OPINION
AMENDMENT UNDER PCT ARTICLE 34(2)(b)**

In response to the Written Opinion mailed 7 January 2005 (07.01.2005), Applicant respectfully requests reconsideration of the above-identified application by the International Preliminary Examining Authority in view of the following remarks and amendments to the claims under PCT Article 34(2)(b). Please substitute the enclosed sheets labeled as pages 14-19 for original pages 14-19, and consider the pages filed herewith to establish the International Preliminary Examination Report.

Claims 1-33 are pending in the application. Claims 1 and 11 have been amended.
Claims 32 and 33 have been added.

REMARKS

In response to the Written Opinion, originally filed claims 1 and 11 have been amended and new claims 32 and 33 have been added.

Claim 1 has been amended to recite an ablation electrode disposed on the shaft, wherein the electrode is convertible from a first configuration in which the electrode has a first axial size and a first radial size to a second configuration in which the electrode has a second axial size and maintains the first radial size.

Claim 11 has been amended to recite a metal element disposed on the shaft which, when exposed, forms a longitudinally continuous outer ablating surface area, wherein the longitudinal extent of the metal element on the shaft is adjustable.

Support for these amendments can be found throughout the application. For example, Figures 2 and 3 show an embodiment of a catheter comprising a metal element disposed on the shaft, wherein the longitudinal extent of the metal element on the shaft is adjustable. A description of the embodiment shown in Figures 2 and 3 may be found at p. 8, line 3 - p. 9, line 18.

The Written Opinion cites a document (US 6,514,246 B1 (D1)) which illustrates an electrode with a retractable sheath that permits adjustment of the exposed area of the electrode. The electrode itself is not said to change in size in Document D1. Similarly, each of the other two cited documents (US 6,488,680 B1 (D2); and WO 95/20360 (D3)) illustrate an electrode with a retractable sheath. The catheter of claim 1 does not require a retractable sheath to adjust any exposed electrode surface because the electrode itself is convertible to different lengths.

Claim 11 is directed to a catheter comprising an ablation electrode comprising a metal element which, when exposed, forms a longitudinally continuous outer ablating surface area, wherein the longitudinal extent of the metal element on a shaft is adjustable. Documents D1 and D2 do not illustrate adjusting the longitudinal extent of a metal element. Document D3 shows an arrangement that permits the sliding of an inner, rod electrode (4) within a cylindrical ring electrode (2) of opposite polarity. The inner electrode (4) of Document D3 remains electrically isolated from cylindrical ring electrode (2) by its insulation sheath (5) and therefore the arrangement does not form a longitudinally continuous outer ablating surface area.

Applicants acknowledge and appreciate the Examiner's finding that dependent claims 2-7, independent claim 16, and dependent claims 17-19 meet the requirements of the PCT with respect to novelty, inventive step, and industrial applicability.

New independent claim 33, directed to a catheter, has been added. The catheter comprises a longitudinal catheter shaft for positioning an ablation electrode within a patient's body. The catheter further comprises an electrically conductive element disposed on the shaft and connectible to an energy supply, an exposed portion of the electrically conductive element

being usable as an ablation electrode, wherein the electrically conductive element is convertible from a first configuration, in which the electrically conductive element has a first axial length and a first radial size along a corresponding first axial length of the shaft, to a second configuration in which the electrically conductive element has a second, longer axial length and maintains the first radial size along the first axial length of the shaft. Support for new claim 33 can be found throughout the application, for example, Figures 2 and 3 and p. 8, line 3 - p. 9, line 18.

Documents D1, D2 and D3 do not illustrate an electrically conductive element that is convertible from a first axial length to a second axial length. Regarding Document D3, the combination of inner electrode (4) and cylindrical ring electrode (2) does not form an electrically conductive element because insulation sheath (5) electrically isolates the two electrodes.

A favorable International Preliminary Report on Patentability in response is requested.

If for any reason this response does not place the application in condition for issuing a favorable International Preliminary Examination Report as to all claims, Applicant requests issuance of a further Written Opinion and an opportunity to respond thereto prior to issuance of the International Preliminary Examination Report. Should there be insufficient time available for issuance of a further Written Opinion, Applicant requests the IPEA to initiate a telephone interview at Applicant's expense, and an opportunity to file a supplemental response to the previous Written Opinion by return fax, pursuant to PCT Article 34(2).

Respectfully submitted,



Eric L. Amundsen, Reg. No. 46,518
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DOCKET NO. B1075.71014WO00

DATE: 7 April 2005

x04/07/05

Express Mail Label No.: EV 493480064-US

CLAIMS

1. A catheter comprising:

5 a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

an ablation electrode disposed on the shaft wherein the electrode is convertible from a first configuration in which the electrode has a first axial size and a first radial size to a second configuration in which the electrode has a second axial size and maintains the first radial size.

10 2. The catheter according to claim 1, wherein the ablation electrode comprises a first electrode portion and a second electrode portion, the second electrode portion having a length and being moveable in the axial direction of the catheter, wherein in the first configuration more of the second electrode portion length is contained within the first electrode portion than in the second configuration.

15 3. The catheter according to claim 2, wherein in the first configuration, the second electrode portion length is fully contained within the first electrode portion.

20 4. The catheter according to claim 2, wherein the ablation electrode comprises a third electrode portion that is at least partially contained within the second electrode portion in the first configuration.

25 5. The catheter according to claim 2, wherein a pull wire is connected to the second electrode portion.

6. The catheter according to claim 1, wherein the ablation electrode is a ring electrode.

30 7. The catheter according to claim 6, wherein the first electrode portion and the second electrode portion are cylindrical.

8. A catheter comprising:

a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

an ablation electrode disposed on the shaft and having an outer surface,

5 wherein the electrode is convertible from a first configuration in which the electrode outer surface has a first axial size and a first radial size to a second configuration in which the electrode outer surface has a second radial size and maintains the first axial size.

9. The catheter according to claim 8, further comprising an inner shaft portion

10 and an outer shaft portion, the outer shaft portion having a longitudinal slot, wherein

the ablation electrode comprises a flexible, electrically-conductive plate having a first end and a second end; and

the first end is attached to the outer shaft portion, the plate passes through the longitudinal slot, and the second end is attached to the inner shaft portion.

15

10. The catheter according to claim 9, wherein rotation of the inner shaft portion relative to the outer shaft portion converts the electrode from the first configuration to the second configuration.

20

11. A catheter comprising:

a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

an ablation electrode comprising a metal element disposed on the shaft which, when exposed, forms a longitudinally continuous outer ablating surface area,

25 wherein the longitudinal extent of the metal element on the shaft is adjustable.

12. The catheter according to claim 11, wherein the electrode is substantially comprised of at least one of: platinum; silver; gold; chromium; aluminum and tungsten.

30

13. The catheter according to claim 11, wherein the electrode is substantially comprised of a combination of at least two of: platinum; silver; gold; chromium; aluminum and tungsten.

14. A catheter comprising:

a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

an ablation electrode comprising a metal sheet disposed on the shaft, the

5 metal sheet forming an electrode outer surface that is substantially continuous along both a longitudinal direction and a circumferential direction; wherein

the electrode is convertible from a first configuration in which the electrode outer surface has a first radial size to a second configuration in which the electrode outer surface has a second radial size.

10

15. The catheter according to claim 14, wherein the ablation electrode is cylindrical.

16. An ablation electrode for ablating tissue, comprising:

15

a first ablation electrode portion configured for mounting on a catheter shaft, the first ablation electrode portion having an outer surface configured to emit electrical energy; and

a second ablation electrode portion configured for mounting on the catheter shaft, the second ablation electrode portion having a surface configured to emit electrical energy; wherein

20

the second ablation electrode portion is moveable from a first position substantially inside the first ablation electrode portion to a second position substantially outside the first ablation electrode portion.

25

17. The ablation electrode according to claim 16, further comprising a third ablation electrode portion configured for mounting on the catheter shaft, the third ablation electrode portion having a surface configured to emit electrical energy, wherein

the third ablation electrode portion is moveable from a first position substantially inside the second ablation electrode portion to a second position substantially outside the second ablation electrode portion.

30

18. The ablation electrode according to claim 16, in combination with a longitudinal catheter shaft for positioning an ablation electrode within a patient's body,

wherein the first ablation electrode and the second ablation electrode are mounted on the catheter shaft.

19. The combination according to claim 18, further comprising a pull wire
5 configured to move the second electrode portion.

20. A catheter shaft comprising:
an outer shaft portion having a longitudinal passage extending through an
outer surface;
10 an inner shaft portion;
an electrode surface with a first end and a second end, the first end coupled
to the inner shaft portion, and the second end coupled to the outer shaft portion, wherein
the electrode surface passes through the longitudinal passage;
one of the outer shaft portion and the inner shaft portion is rotatable relative
15 to the other of the outer shaft portion and the inner shaft portion; and
relative rotation of the inner shaft portion and the outer shaft portion
extends the electrode surface in a radial direction away from the outer shaft portion.

21. The catheter shaft according to claim 20, wherein relative rotation of the
20 inner shaft portion and the outer shaft portion retracts the electrode surface in a radial
direction toward the outer shaft portion.

22. The catheter shaft according to claim 20, wherein the inner shaft portion
and the outer shaft portion are cylindrical.

23. The catheter shaft according to claim 20, wherein the electrode surface
comprises at least one of: platinum; silver; gold; chromium; aluminum and tungsten.

24. A catheter shaft comprising:
30 an outer shaft portion having a passage extending through an outer surface;
an inner shaft portion;
an ablation electrode member configured to pass through the passage; and
a biasing element that biases the electrode member.

25. The catheter shaft according to claim 24, wherein the inner shaft portion is configured to urge the ablation electrode member through the passage in a direction away from the inner shaft portion when the inner shaft portion rotates.

5

26. The catheter shaft according to claim 25, wherein the biasing element is configured to bias the electrode member toward the inner shaft member.

27. The catheter shaft according to claim 26, wherein the passage is a longitudinal slot.

10

28. the catheter shaft according to claim 27, wherein the ablation electrode member is a fin.

15

29. The catheter shaft according to claim 27, comprising two ablation electrode members.

30. The catheter shaft according to claim 27, wherein the two ablation electrode members extend in opposite directions to one another.

20

31. The catheter according to claim 24, wherein the ablation electrode member is comprised substantially of metal.

25

32. A catheter according to claim 16, wherein the first ablation electrode portion and the second ablation electrode portion are electrically connected.

33. A catheter comprising:
a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and

30

an electrically conductive element disposed on the shaft and connectable to an energy supply, an exposed portion of the electrically conductive element being usable as an ablation electrode, wherein the electrically conductive element is convertible from a first configuration, in which the electrically conductive element has a first axial length and

a first radial size along a first axial section of the shaft, to a second configuration in which the electrically conductive element has a second, longer axial length and maintains the first radial size along the first axial section of the shaft.